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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,936	01/07/2002	Dennis Cherek	D00188/70132/NPF	3785
23628	7590	12/23/2003	EXAMINER	
WOLF GREENFIELD & SACKS, PC FEDERAL RESERVE PLAZA 600 ATLANTIC AVENUE BOSTON, MA 02210-2211			WOO, JULIAN W	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 12/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/040,936

Applicant(s)

CHEROK ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22-74 is/are allowed.
- 6) ☒ Claim(s) 1-10, 13, 14 and 20 is/are rejected.
- 7) ☒ Claim(s) 11, 12, 15-19 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 6. 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-10, 13, 14, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Kugel (5,634,931). Kugel discloses, in figures 3-9 and in col. 7, line 36 to col. 9, line 11, an implantable prosthesis for attachment to tissue or muscle, where the prosthesis has first and second layers of material (42, 44) with interstices permitting formation of adhesions and polypropylene mesh (46) for supporting stress induced by patient movement, at least one pocket (70) formed between the first and second layers, and a layer of barrier material (72) that is resistant to the formation of adhesion with tissue or muscle, where at least one pocket with an access opening (66) is defined by attachment of the first and second layers with stitches (51) that do not extend through the layer of barrier material; where the second layer is attached to the layer of barrier material at discrete locations (with the stitches), leaving substantial areas of the second layer free from attachment to the layer of barrier material; where the stitches are made from tissue or muscle adhesion resistant material ("inert synthetic material"), and where the prosthesis includes a peripheral edge (88 in fig. 9) that resists formation of tissue or muscle adhesions.

Allowable Subject Matter

3. Claims 22-74 are allowed.
4. The following is an examiner's statement of reasons for allowance: None of the prior art of record, alone or in combination, an implantable prosthesis for a tissue or muscle defect having, inter alia, at least one layer of mesh or a material with at least a portion of which permits formation of adhesions with tissue or muscle, a peripheral edge, and a pocket formed in the layer; a first reinforcing member coupled to the layer and supporting an outer area of the layer, and a second reinforcing member coupled to the layer and inwardly spaced from the first reinforcing member. The prior art of record also does not disclose, inter alia, that the implantable prosthesis has a first pocket formed in an inner area of the layer and a separate, second pocket formed in an outer area of the layer. The prior art of record does not that the implantable prosthesis has a barrier layer attached to at least a second layer of mesh material attached to a first layer of mesh material, at least one pocket defined by the attachment of the first and second layers of material, and a reinforcing member coupled to one of the layers and arranged to reinforce at least an outer area of the layer.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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5. Claims 11, 12, 15-19, and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses an implantable prosthesis for attachment to tissue or muscle, where the prosthesis has, inter alia, first and second layers of material permitting formation of adhesions, at least one pocket formed between the first and second layers, a layer of barrier material of ePTFE that is resistant to the formation of adhesion with tissue or muscle and covers an entire surface of the second layer, a peripheral edge, and an outer area disposed inwardly of the peripheral edge, where first reinforcing member substantially surrounds and reinforces the outer area, and where a separate, second pocket is formed in the outer area.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Nicolo (6,652,595) teaches an implantable prosthesis for hernia repair.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703) 308-0858. The official FAX number is (703) 872-9306.



Julian W. Woo
Primary Examiner

December 18, 2003